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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,145	05/19/2005	Ke Liu	234872	7496

45733 7590 10/19/2007
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EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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10/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,145	Applicant(s) LIU ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) 15-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment and declaration by Dr. Ke Liu filed 8-29-07 have been entered. Claim 4 has been amended. Claims 1-32 are pending and claims 1-14 are under consideration.

Election/Restrictions

1. This application contains claims 15-32 drawn to an invention nonelected with traverse in the reply filed on 4-19-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' amendment filed 8-29-07 necessitates this new ground of rejection.

The phrase "the 209-2M peptide (SEQ ID NO:5)" in claim 4 is considered new matter. Applicants' point out that the amino acid sequence of the 209-2M is incorporated by reference to Liu et al., 167: 6356-6365 (2001) and Kammula et al., (1999) also teach the 209-2M peptide along with its amino acid sequence (amendment, p. 9). Paragraph [0011] of the specification

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only recites “referred to herein as 209-2M” and paragraph [0013] only recites “[t]he coding sequence of a human IL-2 is available (see, e.g., Liu et al., J. Immunol. 167: 6356-6365(2001)). The specification does not provide a nexus between 209-2M and Liu reference, and the Liu reference is NOT “incorporated by reference” in the specification. Therefore, the content of the Liu reference is NOT considered part of the specification of the instant invention. Further, Liu reference teaches the amino acid sequence of 209-2M as IMDQVPFSV, however, Kammula reference teaches the amino acid sequence of 209-2M as IMQVPFSV. It is unclear which sequence is art recognized amino acid sequence of 209-2M. The specification fails to provide sufficient support for the phrase set forth above. Thus, the phrase “the 209-2M peptide (SEQ ID NO:5)” in claim 4 is considered new matter.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 8-29-07 necessitates this new ground of rejection.

The phrase “the 209-2M peptide (SEQ ID NO:5)” in claim 4 is vague and renders the claim indefinite. As discussed above, the phrase “the 209-2M peptide (SEQ ID NO:5)” in claim 4 is considered new matter. Liu reference teaches the amino acid sequence of 209-2M as IMDQVPFSV, however, Kammula reference teaches the amino acid sequence of 209-2M as IMQVPFSV. It is unclear which sequence is art recognized amino acid sequence of 209-2M.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 and 14 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lupton et al., 1999 (US Patent No. 5,874,556, IDS) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants argue that '556 patent does not disclose obtaining peripheral blood mononuclear cells (PBMCs) from a patient immunized with an antigen of a cancer and stimulating the PBMCs with the antigen of the cancer in vitro (amendment, p. 10). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07. Lupton teaches that "cytotoxic T cells specific to a particular type of tumor can be isolated and administered to a patient having a tumor, with the effect that the CTLs ameliorate the tumor.", and "T cells with apparent tumor specificity can be isolated from human tumors. Such human tumor infiltrating lymphocytes (TILs) have been expanded in vitro and used to treat cancer patients." (e.g. column 2, lines 7-19). Cytotoxic T cells and TILs are lymphocytes that are PMBCs. A human patient having a human tumor is considered a patient immunized with an

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antigen of cancer. Lupton teaches the combination of antigen and IL-2 cause proliferation of primary CD8+ T cells in vitro. Thus, Lupton teaches obtaining peripheral blood mononuclear cells (PBMCs) from a patient immunized with an antigen of a cancer and stimulating the PBMCs with the antigen of the cancer in vitro.

Applicants argue that '556 patent does not disclose retroviral vector that lacks exogenously introduced gene that enables phenotypic selection, in fact, the disclosed retroviral vector comprise the phenotypic selection marker HyTK (column 11, lines 12-16), and the Office does not provide a basis in fact and/or technical reasoning to support the inherent characteristic of the vector (amendment, p. 10). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07. Lupton teaches a recombinant vector comprising a recombinant polynucleotide comprising a nucleotide sequence encoding IL-2 under the control of a transcriptional control region, and expression of IL-2 in activated lymphocyte reduces dependency of the lymphocytes on T helper cells for proliferation (e.g. column 43, claims 1 and 2). The recombinant vector as taught by Lupton does not comprise exogenous gene that enables phenotypic selection. Further, the 1st full paragraph in column 11 only means "preferably" to have a selectable marker, which is not necessarily a marker for "phenotypic selection". Thus, the claims remain rejected for the reasons of record.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3 and 5-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Kwak et al., 2003 (US Patent No. 6,562,347 B1) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

11. Claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Wang et al., 2001 (Exp. Opin. Biol. Ther., Vol. 1, No. 2, p. 277-290, IDS) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

12. Claims 1 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Einerhand et al., 2001 (US Patent No. 6,312,957 B1) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

13. Claims 1, 12 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Roifman, C. M., 2000 (Pediatric Research, Vol. 48, No. 1, p. 6-11) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

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14. Claims 1, 12 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Hattori et al., 1990 (The Journal of Immunology, Vol. 144, No. 10, p. 3809-3815) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

15. Claims 1, 12 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupton et al., 1999 (US Patent No. 5,874,556, IDS) in view of Asami et al., 1996 (European Journal of Haematology, Vol. 57, p. 278-285) and is repeated for the reasons set forth in the preceding Official action mailed 6-4-07. Applicant's arguments filed 8-29-07 have been fully considered but they are not persuasive.

Applicants reiterates the arguments regarding '556 patent as set forth above (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-4-07 and the reasons set forth above.

Conclusion

No claim is allowed.

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'S. Chen', located to the right of the printed name.